

The House of Commons health select committee's report on generic prices - implications for primary care prescribing

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This article considers the House of Commons health select committee report into generic drug prices along with the recent short-term proposals by the Government to control prices. The article focuses on the reimbursement system for pharmacists as the main factor in the steep price rises and their sustained high levels. The challenge for the Government will be to design a reimbursement system that avoids the perverse incentives of the current system and encourages the regular supply of cost-effective generic medicines.

Since the early 1990s numerous attempts have been made to increase the rate of the prescribing of non-proprietary, generic drugs in National Health Service general practice. Although substantial savings were generated through increased generic substitution during the early and mid 1990s, a rapid growth in the prices of many non-proprietary products during the last 18 months of the decade has threatened to add £200m to the annual NHS drugs bill.¹ In response, the House of Commons Select Committee on Health undertook an inquiry into the price of generic drugs.¹ This confirmed that prices of some generic drugs had increased by over 500 per cent over the year to September 1999.

The select committee reported in December, 1999, that increases in generic prices had been caused by problems related to (i) the supply of generic products associated with the closure of one manufacturer and the relocation abroad of two others, (ii) the switch from bulk supply of drugs to individual patient packs as required by European regulations, and (iii) operation of the drug reimbursement system. The committee concluded that "it would be extremely unfortunate if the success of the PCG [primary care group] initiative was undermined by sharp and unpredictable rises in drugs budgets".

In April, 2000, the Government announced a set of proposals to control prices in the main generic drugs markets. This article will discuss those proposals in light of the evidence of the operation of the markets for generics provided in the select committee report. In particular, the article highlights the trade-off in public policy towards generics between encouraging price competition to reduce average prices and promoting price stability for the purposes of PCG budget setting.

The markets for generics

Under current NHS regulations, when a generic drug is prescribed, a pharmacist may dispense any licensed version of the preparation requested, as long as it meets the requirements specified by the prescriber. As a result, cost savings may be generated at the point of dispensing, because pharmacists may decide to dispense the cheapest version of each product requested. In order to promote such savings and to ensure that they primarily accrue to the Exchequer, the Department of Health operates a reimbursement system based upon the Drug Tariff, which reimburses pharmacists at the average price charged for the drug by a "basket" of two major wholesalers and three major manufacturers.

Before publication of the select committee's report, the Department of Health argued that its reimbursement system for generic drugs encouraged competition, as it created a "virtuous circle" in which wholesalers and manufacturers dropped their prices below the reimbursed amount in order to win business. The incentive for a pharmacist is to purchase only when the price offered is less than or equal to the reimbursement price, otherwise he or she loses money. However, despite this mechanism to stimulate price reductions, the select committee stated that, prior to its report, the market for generics had been characterised by "market manipulation, hoarding and collusion" and that the pricing mechanism "not only failed under the pressure of events, but also actively contributed to the problems".

An important confusion in the select committee report and subsequent commentary is the discussion of the market for generics. A market is a situation where consumers can readily substitute one product for another.³ This is clearly not the case for prescribed drugs. Instead there are a series of distinct markets for different generic drugs. This is an important point in considering the market situation and competitive conditions in the supply of the generic drugs which have seen the largest price increases in the last 18 months of the 1990s.

The shortage of generic drugs

Initially, the select committee considered whether the “supply shock” caused by the closure in December, 1998, of the largest manufacturer of generic drugs, Regent GM, led to the rapid growth in market prices. Although there was evidence to suggest that the resulting reduction in supply may have caused a short-term increase in some prices, the committee concluded that the company's closure was not the main source of higher price levels. Instead, it was suggested that the shift to patient packs, the actions of short-line wholesalers (which only supply a limited number of products) and the manipulation of the Category D system (which reimburses pharmacists at the actual price of products in short supply) had a large part in the problem.

Because of EC regulations, generic manufacturers throughout Europe were required to introduce patient packs (each of which had to contain a course of medication in ready-to-dispense form and an explanatory leaflet) for all medicines by January, 1999. As a result, many UK generics manufacturers had to invest heavily in new production facilities, which ultimately increased the cost of the products that they supplied. After hearing evidence from this group, the select committee concluded that the absence of an agreed government policy for the transition period left many manufacturers in a position in which they could manipulate market prices.

The select committee also concluded that the actions of short-line wholesalers had led to increases in prices, as they often entered markets for generics to buy up large quantity of stocks creating shortages and higher prices from which they could benefit. To add to this problem, the committee found that an increasing number of wholesalers and manufacturers reported less than four weeks' supply of particular products triggering Category D status, with the result that pharmacists were no longer forced to seek out the lowest cost products. In support of the hypothesis that this emergency system had been used to manipulate generics prices, the select committee heard that Category D drugs had been subject to the largest price increases and that, over the previous year, the proportion of the products in the category rose from 1 to 16 per cent.

When a drug is listed as Category D, all parts of the supply chain earn higher profits. Economic theory suggests that the generic price will converge to the branded equivalent price⁴ and the evidence provided by the British Generic Manufacturers Association (BGMA) to the select committee supports this. At the higher price, manufacturers and wholesalers earn greater revenues and can offer pharmacists greater discounts on the reimbursement price. There exists little incentive for a manufacturer of a Category D drug to increase production and move their product off the list.

Discussion

In response to the pricing crisis, the Office of Fair Trading (OFT) has begun an inquiry into evidence of anticompetitive behaviour in the market for generic drugs (it is due to be published in the autumn). The present article examines the select committee's assertion that the observed increases in prices were the result of the actions of generics suppliers and inadequacies in the Government's regulatory mechanism. Focus on price rises The select committee cited the rapid growth in the price of some generic products as evidence of market manipulation and a failure of the existing regulatory mechanism. For three main reasons, price rises alone, however dramatic, should not be taken as evidence of the inefficient operation of any market. First, price rises should be seen as an appropriate response to shortages in any market and should not be taken (without further investigation) as evidence of anticompetitive behaviour. Second, increases in the costs of manufacturing should be expected to lead to proportionate increases in prices. Finally, economic theory suggests that market prices will fluctuate until the price at which particular goods may be bought equals the amount that consumers are willing to pay.

Price competition is a dynamic process that requires that manufacturing firms are able to enter easily and exit the different markets for generics.

The BGMA and the British Association of Pharmaceutical Wholesalers (BAPW) claimed that the markets in generics were commodity markets, prone to fluctuations in price according to demand and availability. For example, agricultural commodity markets often see short-term price rises in response to the relative scarcity of a particular commodity.

The very large price increases for generics have occurred in the most concentrated markets, where one or two manufacturers dominate supply. For example, Regent GM was a monopoly supplier of certain generics. However, providing a manufacturer holds a product licence, it is relatively easy to switch production between different drugs (about two to three months). Most manufacturers hold a portfolio of licences, so, even if they do not produce a particular drug at any one time, they should, in theory, provide a strong competitive constraint as potential entrants to the market. This is the crucial question for the OFT investigation: why have the high profits of a Category D drug or a high price generally not attracted entrants to that market thereby increasing supply and driving prices down?

The main point of this article is that the recent rapid rises in the price of some generics can be best understood by focusing on the interactions between the reimbursement system and price competition in the market. The system creates perverse incentives for rational individual firms (manufacturers, wholesalers and pharmacies) to exploit. For example, the incentive for all firms in the supply chain to have a drug listed as Category D but without, it seems, providing incentives for rival firms to enter that market and increase supply. Further, the reimbursement rates set out in the Drug Tariff for Category A drugs follow the market price and act as a ceiling on the level of NHS reimbursement; they are not designed to lead the market and set the price. However, if the price of a generic drug starts to increase, the incentive is for pharmacists to stop buying the product (because the actual price he or she pays is above the reimbursed price) therefore creating shortages of that generic drug.

Regulation of the market Within economics, the failure of any mechanism to encourage economic agents to behave in the ways expected of them has been called “incentive incompatibility.”⁵ In this context, the reimbursement mechanism for generic drugs could be labelled “incentive incompatible” because it eventually failed to encourage suppliers to meet the Government’s objective of the secure and continual supply of cost-effective drugs. As it failed to stop market manipulation, the mechanism was not what economists call “strategy proof”. In other words, a weakness in the regulatory system allowed sellers to act strategically and to find ways of increasing their prices.

Although this behaviour led to rapid increases in prices, many economists would expect suppliers to behave in this way and would not blame the resulting problems on them, but on the inadequacies of the Government’s regulatory system. In consequence, the OFT should not be investigating the strategic behaviour of generic manufacturers and wholesalers. Instead, efforts should be concentrated on examining how weaknesses in the government’s regulatory mechanism may be addressed.⁶

Government’s proposals In April, 2000, the Government proposed a statutory price ceiling for the main generic medicines, corresponding to the average prices in the Drug Tariff for November, 1998, to January, 1999. Lord Hunt (Under-Secretary of State for Health) stated: “I am determined that the NHS will not be ripped off. I am taking action today to cut the price of generic drugs.” He added that “there is no adequate explanation for the steep price rises we have seen — nor for prices remaining high for so long”. These maximum prices would be reviewed after 15 months. At the same time, the Government proposed changes to the reimbursement arrangements for pharmacists and dispensing doctors. In particular, this included the abolition of the Category D arrangement in the Drug Tariff. These proposals were put out to consultation in May and June.

The main problem with imposing a price ceiling on any market is that if the actual market price is above the ceiling, then in basic demand and supply terms, the supply of that commodity will fall. Norton Healthcare, the UK’s biggest manufacturer of generic drugs, threatened to cease production of a number of generics if the ceilings were implemented on the grounds that they would make production uneconomic.⁷ In response to this threat, the Government issued a revised list of proposed maximum prices, some increased by as much as 500 per cent, for a one-week consultation.

After further negotiations, in which some maximum prices were increased, Norton Healthcare's sales and marketing director stated that the company would not now "be forced to discontinue 23 generic lines" (Health Service Journal, July 13, 2000). The maximum prices came into force in August's Drug Tariff.

The rationale for the introduction of the Category D system in the mid 1990s was to ensure the continuity of supplies of medicines to patients (even if this increased the drugs bill of the NHS). Under the Government's initial proposals, this safeguard did not exist to ensure the supply of medicines in the event of price caps creating shortages. Pharmacists would have lost money if they sourced branded drugs for a generic prescription because, without the Category D system, they will only be reimbursed the average basket price of the generic version between November, 1998, and January, 1999.

At the beginning of September, the PSNC negotiated a replacement for Category D of the Drug Tariff with the NHS Executive. In instances when there is a shortage of a generic drug, as agreed between the PSNC, the PPA and the NHSE, contractors will still be able to dispense a branded product and be reimbursed appropriately. Contractors will be advised of shortages as and when they occur, but they will not be listed in the Drug Tariff.

The NHSE has set out certain conditions:

- * Contractors may only endorse a brand during a shortage when they have gone to all reasonable lengths to obtain a product at or below the generic price.**
- * The PPA will audit endorsements to ensure that the product endorsed is the one dispensed.**
- * Prescriptions must be endorsed "no cheaper stock available" or "NCSO", and dated and initialled personally by the pharmacist.**
- * Agreed shortages are in place for one month only unless the NHSE agree that they continue for a further month.**

This system is designed to avoid a situation where the only way for general practitioners to be confident that medicines will be dispensed is to prescribe the branded drug.

Conclusions

The reimbursement mechanism for generic drugs is designed to promote competition between suppliers and to secure lower prices. The mechanism had the desired effect for a number of years, but there was an absence of effective checks on the rapid increase in generic prices during the late-1990s.

There were a number of genuine "market" reasons for this; however, the health select committee concluded that the major part of the explanation of the rapid escalation and sustained high levels of generic drugs prices was in the perverse incentives provided by the reimbursement system to all parts of the generics industry.

In the long term, therefore, primary care expenditure on these products may not depend solely on the competitiveness of the market, but on the Government's ability to design a regulatory mechanism that cannot be manipulated by the suppliers of non-proprietary drugs. However, such a design will face the trade-off between trying to ensure stable prices to help PCG budget control and trying to encourage price competition to reduce average drugs price but at the cost of introducing price volatility.

In the short term, the Government's proposals for price ceilings might produce shortages of certain generic drugs and the abolition of the Category D status will remove pharmacists' incentive to search for all available supplies of a drug in short supply.

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